

Abstract

5 A nutritional composition for diabetics. The composition contains a protein source, a lipid source, and a carbohydrate source. The composition includes a fibre mixture containing a viscous soluble fibre and inulin, a hydrolysate of inulin, or both. The fibre mixture may also contain insoluble fibre. When in liquid form, the nutritional composition has a low viscosity and excellent tube flow rates.



AUSTRALIA

PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

Name of Applicant/s: Societe Des Produits Nestle S.A.

Actual Inventor/s: Veronique JAUSSAN, Claudia ROESSLE, Thomas
SCHWEIZER and Michel BOURGUIGNON

Address of Service: BALDWIN SHELSTON WATERS
60 MARGARET STREET
SYDNEY NSW 2000

Invention Title: "COMPOSITION AND METHOD FOR PROVIDING NUTRITION
TO DIABETICS"

The following statement is a full description of this invention,
including the best method of performing it known to us:-

(File: 20767.00)

Field of the Invention

This invention relates to a nutritional composition suitable for providing nutrition to diabetic patients. The invention also relates to a method for providing nutrition to diabetic patients and to a method for the nutritional management of diabetic symptoms in patients.

Background of the Invention

Diabetes is a general term for a group of metabolic disorders which are characterised by the inability to properly metabolise glucose. This inability is due either to a deficiency of the hormone insulin or to a resistance to the action of insulin. In either case, if untreated, the inability leads to hyperglycaemia and its complications of morbidity and mortality.

Diabetes is usually classified into three clinical classes; diabetes mellitus, gestational diabetes, and impaired glucose tolerance or glucose intolerance. Diabetes mellitus is generally broken down into two types; type I diabetes mellitus and type II diabetes mellitus. Type I diabetes mellitus occurs in individuals who produce little or no insulin and constitutes less than about 10% of the diabetic population. The onset of type I diabetes mellitus usually manifests itself during youth. Type II diabetes mellitus, or non-insulin dependent diabetes mellitus, usually develops after the age of about 30 years and constitutes more than about 90% of the diabetic population. Impaired glucose tolerance, in the clinical setting, often occurs as stress-induced hyperglycaemia.

Often, especially in severe cases, diabetes is treated by the administration of exogenous insulin or antihyperglycaemic agents. However, nutritional management of diabetes is possible and the American Diabetes Association has published guidelines for the nutritional therapy of diabetes. These guidelines suggest that diabetic patients should consume about 20 to 25 g of dietary fibre daily.

Dietary fibres may be classified as soluble and insoluble. Insoluble fibres appear to have little influence on glycemic levels. However, the incorporation of soluble fibres into foods is known reduce postprandial glycaemia in diabetics (Anderson, J.W. and Akanji, A.O.; 1993; "Treatment of Diabetes with High Fiber Diets", CRC Handbook of Dietary Fiber in Human Nutrition, CRC Press Inc, 2nd Edition, pages 443 to 470). Examples of soluble fibres which are believed to

have this property are guar gum, pectin, exanthan gum, and β -glucan. This property makes soluble fibres ideal candidates for incorporation into foods for diabetics.

However, to date, soluble fibres have not been widely used in food for diabetics. A common problem is that many soluble fibres are not very palatable. Also, in the field of clinical nutrition, the incorporation of soluble fibres into enterally administered compositions is extremely difficult since soluble fibres are thickening agents and greatly increase viscosity. Consequently compositions which contain sufficient soluble fibre to significantly reduce postprandial glycaemia are usually too thick and viscous for enterally feeding; especially for patients requiring tube-feeding.

One nutritional composition which offers a solution to the problem is described in US patent 5,292,723. The nutritional composition described in this patent has a carbohydrate component made up of glucose polymers, modified starch, and soluble fibre. Pectin is suggested as a suitable soluble fibre. The nutritional composition has a viscosity of less than 0.05 kg/ms when measured at about 20°C. Further the nutrition composition, when consumed, results in lower glycemic response in patients as compared to glucose of the same energy content.

Any discussion of the prior art throughout the specification should in no way be considered as an admission that such prior art is widely known or forms part of common general knowledge in the field.

It is an object of the present invention to overcome or ameliorate at least one of the disadvantages of the prior art, or to provide a useful alternative.

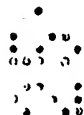
Summary of the Invention

Accordingly, in one aspect, this invention provides a nutritional composition for diabetic patients, the composition comprising a protein source providing about 10% to about 20% of energy, a lipid source providing about 30% to about 50% of energy, a carbohydrate source providing about 35% to about 55% of energy, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both.

It is surprisingly found that the use of a fibre mixture of a viscous soluble fibre and inulin, a hydrolysate of inulin, or both, results in an adequately reduced glycemic response while retaining reasonably low viscosity. Therefore, due to the excellent flow properties, the nutritional composition is ideally suited to be tube-fed to patients. Further, the use of inulin or its hydrolysates provides a substrate for lactic acid bacteria



in the gastro-intestinal tract; leading to beneficial effects in the general health of the patient.



In a second aspect, the present invention provides a liquid nutritional composition for diabetic patients, the composition comprising a protein source, a lipid source, a carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both.

5 In a third aspect, the present invention provides a powdered nutritional composition for diabetic patients, the composition comprising a protein source, a lipid source, a carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both; the powdered nutritional composition being reconstitutable in an aqueous liquid for providing a liquid nutritional composition.

10 The nutritional composition may be in liquid form or in the form of a soluble powder which is reconstituteable in an aqueous liquid to provide a liquid nutritional composition.

Unless the context clearly requires otherwise, throughout the description and the claims, the words 'comprise', 'comprising', and the like are to be construed in an
15 inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

Detailed Description of the Preferred Embodiments

Embodiments of the invention are now described by way of example only. This invention provides a nutritional composition for diabetic patients. The composition
20 contains a protein source, a lipid source, and a carbohydrate source. The carbohydrate source includes a fibre mixture comprising a viscous soluble fibre and inulin. In this specification, the term "soluble fibre" means those dietary fibres which are characterised as soluble using the method of Prosky et al; 1988; J. Assoc. Off. Anal. Chem., 70, 5, 1017. This is the official method of the Associate of Official Analytical Chemists. The
25 term "viscous soluble fibre" means a soluble fibre which is able to increase the viscosity of the contents of the stomach and the small intestine and slow gastric emptying rates.

The viscous soluble fibre may be any suitable soluble fibre which is able to increase the viscosity of the contents of the stomach and the small intestine. Examples of suitable soluble fibres are gums such as guar gum, zanthan gum, and gum arabic,
30 pectin, and β -glucan, or mixtures of these. Pectin and gum arabic are particularly preferred.



The inulin may be provided in the form of a natural extract which is suitable for human consumption. Extracts from chicory are particularly suitable. The extract preferably contains at least 80% by weight of inulin or a hydrolysate of inulin; more preferably at least 90% by weight of inulin of a hydrolysate of inulin. The inulin
5 preferably has a degree of polymerisation of at least about 8; for example about 10 to about 25. Suitable inulin extracts may be obtained from

9
2
0
0
7



Orafti SA of Tirlemont 3300, Belgium under the trade mark "Raftiline". For example, the inulin may be provided in the form of Raftiline®ST which is a fine white powder which contains about 90 to about 94% by weight of inulin, up to about 4% by weight of glucose and fructose, and about 4 to 9% by weight of sucrose. The average degree of polymerisation of the inulin is about 10 to about 12. The inulin may also be in the form of inulin hydrolysates or mixtures of inulin and inulin hydrolysates. Inulin hydrolysates are commonly known as fructooligosaccharides or FOS.

Inulin and its hydrolysates are reported to promote the growth of bifidobacteria in the gastro-intestinal tract and, in certain circumstances prevent or decrease the growth of pathogens such as *Clostridia*. Further, promoting the growth of bifidobacteria is reported to have various other beneficial effects. Moreover, inulin and its hydrolysates may reduce blood glucose levels.

The fibre mixture may also contain a source of insoluble dietary fibre. Suitable sources of insoluble dietary fibres are hull fibres from legumes and grains; for example pea hull fibre, oat hull fibre, barley hull fibre, and soy hull fibre. Pea hull fibre is especially preferred. However any suitable source of insoluble dietary fibre may be used. These sources may also contain some soluble fibre.

The ratio of soluble fibre, including inulin, to insoluble fibre is preferably about 1:3 to about 3:1; more preferably about 1:1 to about 2:1. For example, ratio of soluble fibre, including inulin, to insoluble fibre is preferably about 2:1. Further, the fibre mixture may be present in an amount of about 1.0 g/100ml to about 2.0 g/100ml; for example about 1.3 g/100ml to about 1.7 g/100ml; for example about 1.5 g/100 ml. In a preferred example, the fibre mixture comprises about 0.5 g/100 ml inulin, about 0.5 g/100 ml pectin or gum arabic, and about 0.5 g/100 ml outer pea fibre.

The protein source is preferably a high quality protein source; for example milk protein, whey protein, casein protein, or soy protein, or mixtures of these proteins. The protein source may be in the form of intact protein or may be hydrolyzed. Other protein sources such as rice, pea and oat protein, or mixtures thereof, may also be used. Further, if desired, the protein source may include free amino acids.

The protein source preferably provides about 10% to about 20% of the energy of the composition. For example, the protein source may provide about

12% to about 18% of the energy of the composition; preferably about 15% of the energy of the composition.

5 The carbohydrate source may be any suitable carbohydrate or carbohydrate mixtures. For example, the carbohydrate source may be maltodextrin, modified starch, amylose starch, tapioca starch, corn starch, or fructose, or mixtures thereof. Modified starch is preferred; especially modified tapioca and corn starches. If the carbohydrate source includes maltodextrin, maltodextrin with a low DE is preferred; for example maltodextrin with a DE of 3 or less. Preferably the composition is low in or free from mono- and di-saccharides such as fructose and
10 other exchange sugars, and lactose. For example the composition contains less than about 3 g/l of lactose.

The carbohydrate source, including the viscous soluble fibre and inulin, provides about 35% to about 55% of the energy of the composition; preferably about 40% to about 50% of the energy. For example, the carbohydrate source may
15 provide about 45% of the energy of the composition. The amount of energy provided to the patient by the viscous soluble fibre and inulin is very small.

The lipid source is preferably rich in monounsaturated fatty acids; for example monounsaturated fatty acids may provide at least 50% of energy of the lipid source. Preferably, monounsaturated fat acids provide about 25% to about
20 35% of the energy of the composition; for example about 29 to 30%. The lipid source may contain polyunsaturated fatty acids (omega-3 and omega-6 fatty acids); preferably these polyunsaturated fatty acids provide up to about 10% of the energy of the composition. For example these polyunsaturated fatty acids may provide about 3% to about 10% of the energy of the composition. The lipid profile of the enteral composition is preferably designed to have a polyunsaturated fatty acid
25 omega-6 (n-6) to omega-3 (n-3) ratio of about 4:1 to about 10:1. Saturated fatty acids preferably provide less than 10% of the energy of the composition; for example less than about 7%.

The lipid source may provide about 30% to about 50% of the energy of the
30 composition; preferably about 35% to about 45%. For example, the lipid source may provide about 40% of the energy of the composition.

If desired, the lipid source may include medium chain triglycerides. For example, medium chain triglycerides may make up about 10% to about 50% by weight of the lipid source.

35 Suitable sources of monounsaturated fatty acids are olive oil, sunflower oil rich in oleic acid, rapeseed oil rich in oleic acid, hazelnut oil, safflower oil, and the

like. If medium chain triglycerides are included in the lipid source, fractionated coconut oils are a suitable source of medium chain triglycerides. A mixture of sunflower oil, rapeseed oil and olive oil is preferred.

5 The enteral composition preferably includes a complete vitamin and mineral profile. For example, sufficient vitamins and minerals may be provided to supply about 75% to about 250% of the recommended daily allowance of the vitamins and minerals per 1000 calories of the nutritional composition.

10 The nutritional composition conveniently has an osmolality of about 180 mOsm/l to about 300 mOsm/l; for example about 190 mOsm/l to about 210 mOsm/l.

15 The viscosity of the nutritional composition, when measured at room temperature, is preferably less than about 0.04 kg/ms; especially less than about 0.035 kg/ms. For example, the viscosity of the nutritional composition, when measured at room temperature, may be about 0.015 to about 0.03 kg/ms. Further, the flow rate of the nutritional composition through a standard feeding tube is preferably less than about 150 minutes/l; for example less than about 100 minutes/l.

The energy density of the nutritional composition is preferably about 700 kcal/l to about 1500 kcal/l; for example about 1000 kcal/l.

20 The nutritional composition is preferably in the form of a ready-to-use formulation. In this form, the composition may be fed to a patient via a nasogastric tube, jejunum tube or by having the patient drink it. As such, the nutritional composition may be in a variety of forms; for example as a fruit juice-type beverage, a milk shake-type beverage and the like. However, the nutritional composition may be in soluble powder form to be reconstituted prior to use.

25 Various flavours, sweeteners and other additives may be present. Artificial sweeteners such as acetosulfame and L-aspartyl based sweeteners may be used; for example aspartame.

30 The nutritional composition may be produced as is conventional; for example, by blending together the protein source, the carbohydrate source, and the lipid source. If used, the emulsifiers may be included in the blend. The vitamins and minerals may be added at this point but are usually added later to avoid thermal degradation. Any lipophilic vitamins, emulsifiers and the like may be dissolved into the lipid source prior to blending. Water, preferably water which has been subjected to reverse osmosis, may then be mixed in to form a liquid mixture. The
35 temperature of the water is conveniently about 50°C to about 80°C to aid

dispersal of the ingredients. Commercially available liquefiers may be used to form the liquid mixture.

5 The liquid mixture may then be thermally treated to reduce bacterial loads. For example, the liquid mixture may be rapidly heated to a temperature in the range of about 80°C to about 110°C for about 5 seconds to about 5 minutes. This may be carried out by steam injection or by heat exchanger; for example a plate heat exchanger.

10 The liquid mixture may then be cooled to about 60°C to about 85°C; for example by flash cooling. The liquid mixture is then homogenised; for example in two stages at about 7 MPa to about 40 MPa in the first stage and about 2 MPa to about 14 MPa in the second stage. The homogenised mixture may then be further cooled to add any heat sensitive components; such as vitamins and minerals. The pH and solids content of the homogenised mixture is conveniently standardised at this point.

15 For a product in liquid form, the homogenised mixture is preferably aseptically filled into suitable containers. Aseptic filling of the containers may be carried out by pre-heating the homogenised mixture (for example to about 75 to 85°C) and then injecting steam into the homogenised mixture to raise the temperature to about 140 to 160°C; for example at about 150°C. The
20 homogenised mixture may then be cooled, for example by flash cooling, to a temperature of about 75 to 85°C. The homogenised mixture may then be further homogenised, cooled to about room temperature and filled into containers. Suitable apparatus for carrying out aseptic filling of this nature is commercially available.

25 For a product in powder form, the homogenised mixture is dried to powder; for example by spray drying. Conventional procedures may be used.

The nutritional composition may be used as a nutritional support for patients suffering from metabolic anomalies which make them susceptible to hypo- or hyperglycaemia. For example, the nutritional composition may be used as a
30 nutritional support for patients suffering from type I diabetes mellitus, type II diabetes mellitus, or intolerance to glucose. Further, the nutritional composition may be used as a nutritional support for patients who are at risk of a recurrence of hypo- or hyperglycaemia. The nutritional composition may also be used as nutritional support for post operative patients. The nutritional composition is
35 particularly useful for the nutritional management of diabetic symptoms of diabetic patients.

The amount of the nutritional composition required to be fed to a patient will vary depending upon factors such as the patient's condition, the patient's body weight, the age of the patient, and whether the nutritional composition is the sole source of nutrition. However the required amount may be readily set by a medical practitioner. In general, sufficient of the nutritional composition is administered to provide the patient with about 1 g protein to about 4.0 g protein per kg of body weight per day. For example, an adult patient may be administered about 1.5 g protein to about 2.0 g protein per kg of body weight per day. Further, sufficient of the nutritional composition is administered to provide the patient with up to about 40 g of dietary fibre (insoluble and soluble) per day; for example about 25 g to about 35 g of dietary fibre per day. If the nutritional formula is used as a supplement to other foods, the amount of the nutritional composition that is administered daily may be decreased accordingly.

The nutritional composition may be taken in multiple doses, for example 2 to 5 times, to make up the required daily amount or may taken in a single dose. The nutritional composition may also be fed continuously over a desired period.

Example 1

A ready-to-use nutritional composition is prepared. The nutritional composition includes the following components:

Component	Conc. (/100ml)	Energy (%)
Protein	3.8 g	15
Casein/Soy Protein (1:1)		
Carbohydrate	11.2 g	45
Maltodextrin (low DE)	1.0 g	
Modified Starch	10.2 g	
Soluble fibre including Inulin	1.0 g	
Insoluble fibre	0.5 g	
Lipids	4.4 g	40
Rapeseed oil, Sunflower oil, Olive oil, Glyceryl stearate, Soya lecithin		
Vitamins		
Vitamin A	150 IU	
Vitamin C	10 mg	
Vitamin D	10 IU	
Vitamin E	1.0 mg	
Vitamin K	3.0 µg	
Thiamin	0.1 mg	
Riboflavine	0.12 mg	
Pantothenic acid	0.50 mg	
Vitamin B6	0.14 mg	
Vitamin B12	0.30 µg	
Niacin	1.2 mg	
Folic acid	18 µg	
Biotin	10 µg	
Minerals		
Zinc, Iron, Copper, Magnesium, Manganese, Selenium, Iodine, Potassium, Calcium, Phosphorous, Chloride		

The composition has an osmolarity of 210 mOsm/l and an osmolality of 240 mOsm/kg. The viscosity is 0.023 kg/ms and the free flow rate is less than 70 minutes per 500 ml through standard enteral tubing.

5

Example 2

Eight healthy volunteers, of both sexes, are used in the study. The volunteers are between 20 and 45 years of age and have fasting blood glucose levels of about 70 to about 110 mg/dl. Any volunteer exhibiting the symptoms of diabetes mellitus type I or II or fructose intolerance are excluded.

The study is carried out in two stages, each stage comprising two study days separated by a wash out period of at least 7 days. The stages are also separated by a wash out period of at least 7 days. Prior to each study day, each volunteer consumes an evening meal of pizza, salad and an apple. No alcohol is taken. Then, from 10 pm, each volunteer undergoes an overnight fast. In the morning of the study day, an indwelling catheter is placed on each volunteer. A blood sample is then taken. A meal is then consumed within 10 minutes of the taking of the sample. Further blood samples are taken at 15, 30, 45, 60, 90, 120 and 180 minutes after meal intake. The blood glucose for each sample is analysed by the glucose oxidase method using a COBAS analyser (Hoffmann-La Roche). The insulin level for each sample is measured by radioimmune assay (Pharmacia).

Blood glucose levels are analysed using a two-way ANOVA. The integrated area under the curve (AUC) is calculated using the method of Wolever *et al*; 1986; *Am. J. Clin. Nutr.*, 43, 167-172. The difference between the AUC of the various curves is evaluated using a Wilcoxon matched pairs test or the Hill Armitage test for cross-over design. The glycemic response is considered as different if the AUC curves are statistically different with $p < 0.05$.

Three products are used as the meals; the product of example 1, the Sondalis® Fiber product of Nestlé Clinical Nutrition, and the Fresubin Diabetes product of Fresenius GmbH. Four hundred 400 ml of the product of example 1, 400 ml of the Sondalis® Fiber product, and 444 ml of the Fresubin Diabetes product are consumed in each case to provide a standard energy intake of 400 kcal. All meals contain comparable amounts of minerals and micronutrients.

On the first study day of stage 1, 4 volunteers are fed the product of example 1 and 4 volunteers are fed the Sondalis® Fiber product. The selection of volunteers for any product is random. On the second day of stage 1, the products are reversed. On the first day of stage 2, 4 volunteers are fed the product of example 1 and 4 volunteers are fed the Fresubin Diabetes product. The selection of volunteers for any product is random. On the second day of stage 2, the products are reversed.

The results are as follows:

Time (Minutes)	Plasma Glucose Mean (mmol/l)		
	Product Example 1	Sondalis® Fiber Product	Fresubin Diabetes product
-10	4.88	4.85	5.01
15	5.24	5.56	5.36
30	5.21	6.29	6.31
45	4.70	5.28	5.65
60	4.43	4.80	4.60
90	4.35	4.84	4.28
120	4.64	4.22	4.32
180	4.47	4.06	4.47

The area under the curve results are as follows:

	Product Example 1	Sondalis® Fiber Product	Fresubin Diabetes product
Area at 120 minutes (mmol/l)	37	84	49

The glycemic responses of the product of example 1 and the Fresubin Diabetes product are significantly lower than that of the Sondalis® Fiber; about 30 mmol/l and 50 mmol/l respectively after 120 minutes compared to about 80 mmol/l after 120 minutes. Further, for the product of example 1, blood glucose response is much flatter than that of the Sondalis® Fiber product. The peak change of the product of example 1 is also less than that of the other products. While the glycemic response of the product of example 1 is lower than that of the Fresubin Diabetes product, the differences are not significant. Therefore the product of example 1 is suitable for use with diabetic patients.

None of the patients indicated any symptoms of digestive intolerance.

Example 3

The viscosity and flow rate of the composition of example 1 and the product sold by Fresenius GmbH under the name Fresubin DFN Plus are determined:

5 The viscosity of each composition is determined at 25°C using a Contraves Rheomat according to manufacturer's instructions. The composition of example 1 is filled into a sealed, flexible bag and connected to a stand at a standard height. The Fresubin DFN Plus product, which is in a glass container (its original packing) is connected to a separate stand at the same height. An enteral feeding tube is connected to each container and the time required to deliver 500 ml through the enteral feeding tube is determined. An open reservoir is then connected to each stand and the composition of example 1 poured into one reservoir and the Fresubin DFN Plus product poured into the other. An enteral feeding tube is connected to each reservoir and the time required to deliver 500 ml through the enteral feeding tube is determined.

Property	Composition of example 1	Fresubin DFN Plus product
Viscosity (kg/ms)	0.023	0.035
Free Flow Rate (min/500ml)		
- Original Container	66	158
- Open reservoir	60	129

The results indicate that the composition of example 1 has a superior flow rate.

Example 4

A ready-to-use nutritional composition is prepared. The nutritional composition includes the following components:

Component	Conc. (/100ml)	Energy (%)
Protein	3.8 g	15
Casein/Soy Protein (1:1)		
Carbohydrate	11.2 g	45
Maltodextrin (low DE)	1.0 g	
Modified tapioca and corn starch	10.2 g	
Soluble fibre including Inulin	1.0 g	
Insoluble fibre	0.5 g	
Lipids	4.4 g	40
Rapeseed oil, Sunflower oil, Olive oil, Mono- and di-glycerides (E471)		
Vitamins and minerals as in example 1		

The composition has an osmolarity of 190 mOsm/l. The viscosity is about 0.023 kg/ms and the free flow rate is less than about 70 minutes per 500 ml through standard enteral tubing. Monounsaturated fatty acids provide about 29% of energy, polyunsaturated fatty acids provide about 6% of energy, and saturated fatty acids provide about 5% of energy.

It will be understood that numerous modifications may be made to the specific embodiments described above without departing from the scope of the invention as defined in the claims.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A nutritional composition for diabetic patients, the composition comprising a protein source providing about 10% to about 20% of energy, a lipid source providing about 30% to about 50% of energy, a carbohydrate source providing about 35% to about 55% of energy, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both.
2. A liquid nutritional composition for diabetic patients, the composition comprising a protein source, a lipid source, a carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both.
3. A nutritional composition according to claim 2 which has a viscosity, when measured at room temperature, of 0.015 to 0.03 kg/ms.
4. A powdered nutritional composition for diabetic patients, the composition comprising a protein source, a lipid source, a carbohydrate source, and a fibre mixture including a viscous soluble fibre and inulin, a hydrolysate of inulin, or both; the powdered nutritional composition being reconstitutable in an aqueous liquid for providing a liquid nutritional composition.
5. A nutritional composition according to any of claims 1 to 4 in which the fibre mixture further includes a source of insoluble dietary fibre.
6. A nutritional composition according to claim 5 in which the source of insoluble dietary fibre is pea hull fibre.
7. A nutritional composition according to claim 5 or claim 6 in which the ratio of soluble fibre, including inulin, to insoluble fibre is 1:3 to 3:1.
8. A nutritional composition according to any of claims 1 to 4 in which the fibre mixture comprises about 0.5 g/100 ml inulin, about 0.5 g/100 ml pectin or gum arabic, and about 0.5 g/100 ml pea hull fibre.

9. A nutritional composition according to any of claims 1 to 8 in which the lipid source includes monounsaturated fatty acids which provide about 25% to about 35% of the energy of the composition.
- 5 10. A nutritional composition according to claim 9 in which the lipid source further includes saturated fatty acids providing less than 10% of the energy of the composition.
- 10 11. A nutritional composition for diabetic patients substantially as herein described with reference to any one of the examples but excluding comparatives.
12. A powdered nutritional composition for diabetic patients substantially as herein described with reference to any one of the examples but excluding comparatives.

DATED this 22nd Day of June, 1998
SOCIETE DES PRODUITS NESTLE S.A.

Attorney: IAN T ERNST
Fellow Institute of Patent Attorneys of Australia
of BALDWIN SHELSTON WATERS